

Exhibit H

Ernest J. Ferris, MD • Timothy C. McCowan, MD² • Danna K. Carver, RN
David R. McFarland, MD

Percutaneous Inferior Vena Caval Filters: Follow-up of Seven Designs in 320 Patients¹

Three hundred twenty-four percutaneous inferior vena caval (IVC) filters of different designs were placed in 320 patients from April 1985 through June 1992. No acute mortality or substantial morbidity was attributed to filter placement. Radiologic or pathologic follow-up data were obtained in 227 (71%) patients (230 filters); clinical follow-up data only were obtained in 50 (16%) patients (50 filters). One hundred twenty (43%) patients died; post-filter-placement pulmonary emboli (PE) were related to the cause of death in eight. At IVC filter imaging studies, 26 of 137 (19%) filters demonstrated caval thrombus; 12 of 132 (9%) filters had delayed penetration through the IVC wall of greater than 3 mm; 13 of 230 (6%) filters migrated more than 1 cm; and five of 230 (2%) filters had fracture of a strut or leg. Deep venous thrombosis (DVT) at the insertion puncture site or in the lower extremity was noted in 26 of 117 (22%) cases of filter placement. Among patients without imaging studies, clinical suspicion of complications included PE in four patients, IVC thrombus in 14 patients, and lower-extremity DVT in 10 patients. Long-term clinical and radiologic follow-up of all IVC filters is indicated due to the relatively high prevalence of some complications.

Index terms: Interventional procedures, complications, 93.751, 944.77, 982.458, 982.751 • Venae cavae, filters, 982.456 • Venae cavae, interventional procedure, 982.456, 982.458

Radiology 1993; 188:851-856

¹ From the Department of Radiology, University of Arkansas for Medical Sciences, Mail Slot 556, 4301 W Markham St, Little Rock, AR 72205. From the 1992 RSNA annual scientific assembly. Received October 8, 1992; revision requested November 5; revision received February 16, 1993; accepted February 24. Address reprint requests to E.J.F.

² Current address: Department of Radiology, University of Nebraska Medical Center, Omaha.
© RSNA, 1993

TRANSVENOUS interruption of the inferior vena cava (IVC) for the prevention of pulmonary embolism became clinically feasible with the introduction of the Mobin-Uddin filter in 1967 (1). Although the Mobin-Uddin filter solved many of the problems of caval interruption, especially the morbidity and mortality associated with surgical clipping, plication, or ligation of the IVC, complications still occurred, most notably a 60%-70% rate of caval occlusion with venous stasis sequelae after filter insertion (2,3). The Kimray-Greenfield (KG) filter became available soon after the Mobin-Uddin filter (4). The higher rate of caval patency (approximately 95%) for the KG filter soon made it the favored device for transvenous caval interruption (5,6).

Since the filter introducers or carriers of the Mobin-Uddin and KG filters were relatively large (22 to 24 F), initially both filters were routinely inserted via the femoral or internal jugular vein by means of surgically created phlebectomies. Percutaneous insertion of the standard stainless-steel KG filter became popular in the 1980s (7-10). The large size of the percutaneous tract needed for placement of the introducer sheath (29.5 F) led to concern about a high rate of insertion site complications, particularly femoral vein thrombosis (11,12). Although there is disagreement regarding the actual rate of these access site complications, their significance, and the ability to reduce them with different insertion techniques or new devices, medical companies have designed different IVC filters specifically for percutaneous insertion with smaller introducer sheaths (13-20).

This report summarizes our clinical experience with seven different designs of percutaneous IVC filters: Bird's Nest type I (BN-I) (Cook, Bloomington, Ind), Bird's Nest type II (BN-II) (Cook), Amplatz (A) (Cook), nitinol (N) (Nitinol Medical Technolo-

gies, Woburn, Mass), Titanium Greenfield original design (TG) (Medi-tech/Boston Scientific, Watertown, Mass), Titanium Greenfield modified hook design (TGMH) (Medi-tech/Boston Scientific), and Vena-Tech (VT) (B. Braun Vena-Tech, Evanston, Ill). Although the stainless steel KG filter has been used (by means of both surgical cutdown and percutaneous insertion) at our institution, this filter, unlike the others analyzed in this article, was not specifically designed for percutaneous insertion and is not included in our study. This report emphasizes the postplacement, long-term complications of IVC filters, including recurrent pulmonary embolism (PE), IVC thrombus, penetration of the IVC by filter components, filter migration, filter fracture, and new or increased lower extremity deep venous thrombosis (DVT) after filter insertion.

MATERIALS AND METHODS

Demographics

From April 1985 through June 1992, 324 IVC filters were inserted in 320 patients at the University Hospital of the University of Arkansas for Medical Sciences and the John L. McClellan Memorial Veterans Administration Hospital. Informed consent was obtained for all filter placements and all follow-up studies, and any investigational filters were inserted with approval of each institution's Investigation Review Board. The number and types of filters are detailed in Table 1. Four patients each received two IVC filters. The average patient age at the time of filter insertion was 63 years (range, 15-95 years).

One hundred forty patients had a known malignancy at the time of filter

Abbreviations: A = Amplatz, BN-I = Bird's Nest type I, BN-II = Bird's Nest type II, DVT = deep venous thrombosis, IVC = inferior vena cava, KG = Kimray-Greenfield, N = nitinol, PE = pulmonary embolism, TG = Titanium Greenfield, TGMH = Titanium Greenfield modified hook design, VT = Vena-Tech.

placement. Of the 324 filters inserted, 250 (77%) were inserted because of a contraindication to anticoagulation therapy in patients with known PE or DVT involving the above-knee popliteal, superficial femoral, common femoral, or iliac veins, or IVC. Forty-four (14%) filters were inserted due to a failure or complication of anticoagulant therapy. Thirty (9%) filters were inserted prophylactically, primarily for venous thrombi in large veins in conjunction with poor cardiopulmonary reserve or expected long-term immobility.

Postplacement follow-up data were available for 277 (87%) of the 320 patients (280 filters). Forty-three patients (44 filters) were lost to follow-up after filter insertion. Of the 280 filters with follow-up studies, 230 had radiologic or pathologic examinations in addition to clinical evaluation. Fifty patients (50 filters) had only clinical follow-up (no radiologic or pathologic evaluation). The average time to the last postplacement follow-up was 404 days (range, 1–2,392 days).

Definitions

Patients with follow-up were evaluated for the seven filter complications listed below. Only cases of appropriate and definitive radiologic or pathologic studies were used to compute complication rates. Most patients underwent more than one study on more than one occasion. All cases with radiologic follow-up had at least an abdominal radiograph. Complications were documented as clinically symptomatic or asymptomatic. Data about patients with clinically suspected complications but without definitive findings of radiologic or pathologic studies were summarized separately. In the four patients with more than one filter, the complication was attributed to a single, particular filter, if possible (eg, a complication prior to placement of the second filter); if potentially related to either filter, the complication was attributed to both filters.

Death.—Cause of death was obtained from death certificates or autopsy reports. Only autopsy results were considered definitive for the diagnosis of death from or related to PE.

Recurrent PE.—Pulmonary arteriography demonstrating acute PE; a change in a ventilation-perfusion lung scan to high probability from normal, low, or intermediate probability; and autopsy were considered definitive studies for recurrent PE. Patients were not routinely or systematically screened for recurrent PE.

IVC thrombus.—One hundred thirty-seven filters had definitive imaging or pathologic studies to diagnose IVC thrombus. These studies were obtained with abdominal ultrasound (US), contrast material-enhanced computed tomography (CT), intravascular US, or contrast-enhanced venacavography. The presence of any thrombus in the IVC or filter, no matter the size, was considered positive for IVC thrombus.

IVC penetration.—Filter components extending more than 3 mm outside the wall

Table 1
Percutaneous Filter Placement and Follow-up, by Filter Type

Filter Type	Total No. Inserted	No. of Filters, by Follow-up			Average Length of Follow-up/Range (d)*
		Radiologic or Pathologic	Clinical Only	Not Available	
BN-I	32	25	4	3	1,007/1–2,392
BN-II	46	33	9	4	440/1–1,297
A	30	27	3	0	673/1–1,910
N	21	17	2	2	470/1–1,200
VT	113	72	24	17	190/1–906
TG	10	6	3	1	380/5–1,075
TGMH	72	50	5	17	101/1–673
Overall	324†	230	50	44	404/1–2,392

* Number of days was calculated only for patients with follow-up at least 1 day after placement of IVC filter.

† Total patients = 320. Four patients received two filters each.

of the IVC as determined by using CT (contrast-enhanced or unenhanced images), venacavography, abdominal duplex US, a combination of intravascular US and fluoroscopy, or autopsy were considered positive for penetration. Acute penetrations during insertion are considered in the placement problems category. One hundred thirty-two filters had appropriate diagnostic radiologic studies. Involvement of adjacent organs or structures was evaluated with CT.

Migration.—Change in filter position, either cranial or caudal, of more than 1 cm as seen at abdominal radiography, CT, or venacavography was considered positive for filter migration. Two hundred thirty filters were evaluated for filter migration.

Filter fracture.—Abdominal radiographs of 230 filters were evaluated for disruption of filter components.

New or increased DVT.—Duplex sonography with compression or venography were considered definitive studies for DVT. In some cases, only the filter insertion puncture site was studied. Patients were not routinely or systematically screened for DVT, and patients with full lower-extremity imaging studies were usually referred due to clinical suspicion of DVT. One hundred seventeen filters had definitive studies after insertion. Only patients with new DVT or increased DVT after placement of the filter were listed as having positive findings.

Insertion problems.—On the basis of information from the radiologist or radiologic report and radiographs, difficulty with insertion of each of the filters was divided into three categories: filter-related (eg, malfunction of the filter without known patient or technical problems, incomplete filter opening, or filter tilt of greater than 15° from the axis of the IVC), patient-related (anatomic abnormalities increasing the difficulty of filter placement), and technique-related (eg, operator error during insertion causing caval penetration).

Clinical complications.—Fifty patients (50 filters) had clinical follow-up without imaging studies to confirm possible compli-

cations. Clinical suspicion was usually based on physical findings or symptoms, such as onset of lower-extremity swelling (unilateral for DVT, bilateral for caval thrombus) without known congestive heart failure, cellulitis, or trauma, or onset of pleuritic chest pain, hemoptysis, and dyspnea for recurrent PE. Patients with death certificates indicating possible filter complications without autopsy confirmation were included in the clinical totals but were not included in the statistics of the filter complications.

RESULTS

The results for each filter complication category are given below for all filters. Complications divided by filter type are given for some categories in Table 2.

Death.—Of 277 patients followed up, 120 (43%) died. Most of these deaths were attributable to cancer and its inherent long- and short-term complications. PE was listed as the cause of death, or a major contributing factor, in autopsy results in eight patients. Various other causes such as myocardial infarction, congestive heart failure, hemorrhage, and fluid imbalance were listed as contributory or main causes of death in these patients.

Recurrent PE.—In addition to the eight patients with PE proved at autopsy, three other patients had recurrent PE demonstrated by using high-probability ventilation-perfusion lung scanning. One of these three patients had a second filter placed and later died of massive recurrent PE. This patient is also included in the group of eight patients who died of PE. The time from filter placement to documented recurrent PE ranged from 2 to 1,111 days, with an average of 226 days. Specifically, recurrent PE was

Table 2
Percutan

Cu
PE de
Recur
IVC th
IVC pe
Migrat
Fractu
New C
Site
Ipsil:
Cont
Bilat
Not :

† Numbe
‡ Include:
§ First nu
age of studi

document
ters, at 45
ly; one BN
filters, 2, 2
ly; one N f
294 days; c
two TGMH
respecti
IVC i
definitive
26 (19%) h
the IVC or
ters (all wi
thrombus c
the IVC) w
lateral low
13 patients
(the smalle
mm at intra
symptoms.

IVC penet
(9%) filters
penetration
mm or mor
IVC at post
filters (all n
structures:
one, the ilia
grated caud
the iliac vei
portion of t
tients had s
penetration
penetration
Seven cases
during inse
these statist
insertion pr

Migrat
filters h
follow-up. s
cephalic, an

Table 2
Percutaneous Filter Complications, by Filter Type

Complications	BN-I (n = 32)	BN-II (n = 46)	A (n = 30)	N (n = 21)	VT (n = 113)	TG (n = 10)	TGMH (n = 72)	Total* (n = 324)
PE deaths	1	1	2	1	1	0	2	8
Recurrent PE†	2	1	3	1	1	1	2	11
IVC thrombus‡	4/23 (17)	5/24 (21)	5/22 (23)	3/12 (25)	7/28 (25)	0/6 (0)	2/22 (9)	26/137 (19)
IVC penetration‡	1/22 (5)	1/16 (6)	3/26 (12)	4/12 (33)	0/28 (0)	3/6 (50)	0/22 (0)	12/132 (9)
Migration‡	3/26 (12)	0/32 (0)	0/27 (0)	2/17 (12)	2/72 (3)	3/6 (50)	3/50 (6)	13/230 (6)
Fracture‡	1/26 (4)	1/32 (3)	0/27 (0)	2/17 (12)	1/72 (1)	0/6 (0)	0/50 (0)	5/230 (2)
New DVT‡	4/27 (15)	3/15 (20)	4/21 (19)	1/9 (11)	8/25 (32)	1/6 (17)	5/14 (36)	26/117 (22)
Site								
Ipsilateral	2	2	1	0	4	0	3	12
Contralateral	0	0	1	0	0	0	0	1
Bilateral	0	0	2	1	4	1	1	9
Not available	2	1	0	0	0	0	1	4

* Number of filters studied for complications in 320 patients. Four patients each received two filters.

† Includes deaths related to PE.

‡ First number is number of complications; second number is number of studies performed to evaluate for complications. Number in parentheses is percentage of studies that showed complications.

documented as follows: two BN-I filters, at 45 and 1,111 days, respectively; one BN-II filter, 280 days; three A filters, 2, 29, and 509 days, respectively; one N filter, 7 days; one VT filter, 294 days; one TG filter, 35 days; and two TGMH filters, 19 and 150 days, respectively.

IVC thrombus.—Of 137 filters with definitive imaging studies of the IVC, 26 (19%) had thrombus detected in the IVC or filter. Twelve of these filters (all with more extensive IVC thrombus or complete occlusion of the IVC) were symptomatic with bilateral lower-extremity swelling. The 13 patients with small IVC thrombi (the smallest was approximately 3 mm at intravascular US) had no symptoms.

IVC penetration.—Twelve of 132 (9%) filters were documented to have penetration of filter components of 3 mm or more through the wall of the IVC at postinsertion follow-up. Four filters (all nitinol) penetrated adjacent structures: two, the abdominal aorta; one, the iliac artery (the filter migrated caudad to the confluence of the iliac veins); and one, the third portion of the duodenum. No patients had symptoms related to caval penetration, including those with penetration into adjacent structures. Seven cases of acute caval penetration during insertion are not included in these statistics but are listed under insertion problems.

Migration.—Thirteen of 230 (6%) filters had documented migration at follow-up. Seven migrations were cephalic, and six were caudal. Of

three BN-I filters that migrated to the right atrium or ventricle, two migrations were discovered within 24 hours: One filter was removed percutaneously and a second filter was placed; the second migrated filter was repositioned in the intrahepatic IVC with a tip-deflecting wire. The third BN-I filter migration to the right ventricle was seen at 1-month follow-up. Attempts to remove or reposition the filter were unsuccessful. The patient has been followed up for 6 years, and no problems related to the filter have been found.

One N filter was found in the left pulmonary artery at 1-month follow-up. No attempt was made to remove the filter. The patient is doing well at almost 4 years after insertion and has normal pulmonary blood flow at ventilation-perfusion lung scanning. One N filter migrated caudad to the confluence of the iliac veins. This filter also showed caval perforation with penetration of the adjacent iliac artery. No attempts were made to remove the filter. No patient had clinical symptoms related to filter migration.

Filter fracture.—Five of 230 (2%) filters had a fracture of a strut or leg documented at follow-up. No historical incidents such as trauma could be found to account for the filter fractures. No patient had symptoms of filter fractures.

New or increased DVT.—Twenty-six of 117 (22%) filter insertions with follow-up lower-extremity US or venography had evidence of new DVT or extension of previous DVT in the lower extremity or at the puncture

site. Fifteen patients had symptoms of DVT, two had no symptoms, and clinical status information was not available for nine patients. Most cases were ipsilateral or bilateral (Table 2).

Insertion problems.—No acute deaths and no substantial morbidity were associated with filter insertion. No patient needed operative intervention to correct an insertion problem. Thirty-one filter-related problems of insertion occurred: difficulty adequately attaching filter anchoring struts to caval wall (BN-I, $n = 2$; BN-II, $n = 5$); difficulty releasing filter from delivery system (BN-I, $n = 1$; N, $n = 1$); incomplete filter opening or clustering of filter legs (VT, $n = 13$; TGMH, $n = 5$); and filter tilting (TGMH, $n = 4$). Patient-related insertion problems occurred in eight patients and were usually due to abnormal or distorted patient anatomy (eg, compression from adjacent tumor) or an unusually small- or large-diameter cava, making filter placement subjectively more difficult. All patients with difficult anatomy successfully received IVC filters. The filters involved were BN-I ($n = 1$), BN-II ($n = 1$), VT ($n = 2$), TGMH ($n = 1$), A ($n = 1$), and N ($n = 2$). Technique-related insertion problems occurred in 24 cases: prolapse of filter wires or components (BN-I, $n = 3$; BN-II, $n = 6$); acute penetration of the IVC (BN-II, $n = 1$; N, $n = 1$; TGMH, $n = 5$); incomplete filter opening or leg clustering due to suboptimal placement location (VT, $n = 1$; TGMH, $n = 5$); filter inserted inversely (VT, $n = 1$); and filter jammed in delivery device (N, $n = 1$).

Clinical findings.—Of the 50 patients (50 filters) with only clinical follow-up, four patients were thought to have recurrent PE (two underwent empiric treatment despite indeterminate ventilation-perfusion lung scans and no pulmonary arteriograms), 14 were thought to have caval thrombus, and 10 were believed to have new lower-extremity DVT. No imaging studies were available to confirm these clinical suspicions, and these patients were not included in the statistics of filter complications.

DISCUSSION

From a theoretical viewpoint, one would prefer a transvenous filter that has a small introducer, is technically easy to insert, is mechanically and biologically stable, has a low rate of short- and long-term complications, and effectively protects against major embolic disease. While the ideal filter has yet to be produced, the new vena caval filters specifically designed for percutaneous transvenous insertion have facilitated placement and reduced the immediate morbidity and mortality of surgical insertion (13,14, 21–23). Ease of placement, however, is only one of the important reasons for choosing a particular type of filter.

The incidence of PE after filter placement remains problematic. Routine follow-up pulmonary angiography and ventilation-perfusion lung scanning are invasive or expensive, or both. Most filter patients are subjected to these studies only if there is a clinical suspicion of PE. Silent PE will be missed if these studies are not performed at the time of the embolic event. Reported recurrent PE rates for the KG filter have been approximately 5% (5–10,13,14,24). This rate is not significantly different from reported PE rates of 2%–7% for percutaneous filters (13,14,16–20,25–27).

All of these studies, including this one, have limitations in the accuracy of the reported incidence of PE as discussed above. Eleven of the 277 (4%) patients (280 filters) in this report with available follow-up had documented PE after filter insertion. Even considering the additional four patients with only a clinical suspicion of PE (for a total of 15 of 277 patients, or 5%), the rate of PE in this series is comparable with reported rates of PE for the various filter studies cited above. No notable difference in the rates of PE was apparent among the different filter types we reviewed.

Both the diagnosis and even the definition of caval thrombosis after

filter placement is controversial. It is difficult in many cases to determine the clinical significance or cause (thrombosis versus embolus) of thrombus identified in the filter or IVC. The diagnosis of caval thrombus usually requires invasive (vena cavaogram or intravascular US) or expensive (contrast-enhanced CT) studies (28,29). Abdominal US can be a useful imaging tool to detect caval thrombus, but some examinations are technically inadequate, and the reliability of detecting small thrombi is not known (30). Without routine screening, clinically silent caval thrombi would be missed.

We have elected to classify all cases of thrombus detected in the IVC or filter as positive for caval thrombus. This classification includes even small thrombi, but there are no data to document the clinical significance of this finding. Caval thrombus may be significant as a source for small recurrent PE or as a nidus for more extensive caval thrombosis. The prevalence of caval thrombus in this series was 19%. Twelve of these 26 cases were symptomatic. More extensive caval thrombus or complete occlusion of the IVC was associated with a higher incidence of symptoms. The TG and TGMH filters had the lowest incidence of caval thrombus: 0% and 9%, respectively. These numbers should be viewed with caution, however, since the thrombus rate for these two filters may be artificially low compared with those of the other percutaneous filters because of the substantially shorter follow-up period (and, therefore, fewer overall appropriate imaging studies) for the TG and TGMH filters. Our series demonstrates an incidence of caval thrombus that compares with the 7%–22% reported in other series, but our overall rate is somewhat higher than the 3%–5% rate for the KG filter reported by most authors (5–10,13,14,16–20,25–27,31,32). This may reflect our more liberal definition of caval thrombus, more intensive follow-up, or a true difference in thrombus rates among the filter types.

Penetration of the wall of the IVC by components of caval filters is a known complication (13,14,32–34). Twelve perforations occurred in our series. Four cases, all N filters, involved adjacent structures: the abdominal aorta in two, iliac artery in one, and duodenum in one. The TG filter had a 50% rate of caval penetration in the six patients in our series. Other reports of caval penetration led to the redesign of this filter (35,36). No patient in our series

had clinical symptoms related to caval perforation.

Filter migration occurred in 13 of 230 (5%) filters studied. Most migrations were clinically insignificant, as they were just greater than the 1-cm cephalic or caudal change in location that was our criterion for filter migration. All BN migrations in our experience were among the BN-I filters (16,37). The anchoring struts have been redesigned (BN-II), and no migrations of the new filter design were seen in this series. Although fewer migrations have been reported with the BN-II filter, massive thromboembolism has been reported to cause cephalic migration of this filter (16,38).

The high rate of TG migration in our series corresponds with a known problem of this filter, which may also be related to the high incidence of TG filter caval penetration (35,36). All three TG filter migrations in this series also penetrated the IVC. Despite some very dramatic filter migrations (to the pulmonary artery and right side of the heart), no patients with filter migrations had symptoms, and the migrations were discovered only at radiologic follow-up studies. The two filter types with the most important migration problems (BN-I and TG) have been redesigned. When compared with other reports of filter insertions, including the KG filter, migration does not seem to be a major problem with the percutaneously inserted filters used in this series (5,6, 13,14,16–19,25–27,31,32,35–37).

Fractures of filter components are relatively rare (5,6,13,14,16–19,25,39, 40–42). Five of the 230 (2%) filters we studied had an identified fracture of a filter strut or leg at follow-up. These fractures occurred in one BN-I and one BN-II filter, two N filters, and one VT filter. The N fractures occurred in filters that showed leg splaying. No traumatic pathogeneses were apparent to account for the filter fractures. All fractures were asymptomatic. Since the filter anchoring components are usually fixed with endothelium at 2 weeks, there is probably little chance of embolization. Whether the fracture of a filter strut or leg decreases the protection from PE is unknown.

New or increased lower-extremity DVT was documented in 26 of 117 (22%) patients studied with venography or duplex US. Insertion site complications, notably DVT, were initially a major concern with the percutaneous placement of the KG filter (11,12). The need for concern remains controversial, and access site thrombosis

rates for the method (7–15.4%) that the new filter design had a lower prevalence of lower extremity DVT than the smallest filter design.

The relationship between filter placement and the prevalence of lower extremity DVT is likely to be missed. Adequate follow-up of the status (apparent filter term antithrombotic rate of long therapy placement).

Placement encountered depend on patient anatomy (47,48). Insertion and no migration placement referred for an IVC filter documented opening of (49,50). Most were unimpaired by these patients.

The TGMH clustering of the filter at the anterior half of the femoral vein completely of the intro against the left femoral the cluster most every the filter in the leg space the shape of acute penetration (n = 5) should caution, since hooks bare inferior for filter with filters at struts was also occurred in

to caval
in 10
ically,
the 1-cm
location
er migra-
r experi-
ilters
have
d no mi-
sign were
fewer
ed with
mboem-
cause
ter (16,38).
tion in
a known
may also
nce of TG
5). All
this series
pite
grations
d right
s with
ms, and
red only
es. The
it impor-
-I and
V
s, r
filter,
e a major
ously in-
es (5,6,
7).
ents are
9,25,39,
ilters we
cture of a
. These
-I and
, and one
urred in
ng. No
e appar-
-atures.
atic.
nponents
elium at
tle
ther the
de-
E is un-
remity
of 117
zenogra-
site com-
e initially
e-
2).
s contro-
bosis

rates for the KG filter have ranged from 10% to 41%, depending on the methods of placement and evaluation (7-15,43,44). It has been suggested that the new smaller-diameter percutaneous filters offer a significant reduction in postplacement lower-extremity DVT (15,45,46). The lowest prevalence of DVT in our filter population was with the N filter, which has the smallest-diameter introducer.

The relatively high prevalence of symptomatic DVT in this study (24 patients) may be related to the method of follow-up; that is, not every patient was routinely studied, and patients with symptoms were more likely to be referred for imaging tests. Patients with asymptomatic DVT who were not studied would have been missed. Additionally, we did not evaluate the prevalence of DVT in relation to the patient's anticoagulant status (approximately 30% of postinsertion filter patients were given long-term anticoagulation therapy). The rate of long-term anticoagulation therapy may affect the rate of postplacement DVT.

Placement difficulties have been encountered with all caval filters and depend on operator technique, patient anatomy, and filter design (47,48). Despite 63 problems related to insertion, no substantial morbidity and no mortality were related to placement of the filters. All patients referred for filter placement received an IVC filter. We noted a previously documented problem of incomplete opening of the VT filter in 13 cases (49,50). Most incomplete openings were unimportant, and no specific interventions were performed in these patients to improve filter opening.

The TGMH filter had noticeable clustering of filter legs in 10 cases. In half of these cases, however, the operator who placed the filter was not completely satisfied with the location of the introducer sheath (usually against the lateral caval wall via the left femoral artery) and considered the clustering a technical error. In almost every case, CT of the IVC with the filter in position showed acceptable leg spacing when compared to the shape of the IVC. The number of acute penetrations by the TGMH filter ($n = 5$) should also be viewed with caution, since in four of the cases the hooks barely exceeded the 3-mm criterion for penetration. Prolapse of filter wires of the BN-I and BN-II filters above the upper anchoring struts was a technical problem that occurred in nine patients. No patients

are known to have been adversely affected by the prolapsed filter components.

Despite the difficulties in identifying the complications of IVC filters, the newer percutaneous IVC filters appear to adequately prevent PE and seem to have complications rates comparable with the older KG filter. Only the incidence of caval thrombus (except with the TG or TGMH percutaneous filters) appears higher. Whether this represents a significant difference among filter types or reflects the more intensive follow-up given some of the percutaneous filter designs remains to be proved. Some complications occur many days or years after filter placement, and many complications, such as filter fracture, migration, and caval perforation, can be asymptomatic. In view of these facts, in patients with short life expectancy such as those with terminal malignancies, long-term filter complication rates may be less important than ease and safety of insertion. In patients with longer expected life spans, the lack of delayed complications becomes more important. We believe continuous, long-term follow-up, both clinical and radiologic, of these permanently implanted devices is essential. A national filter registry or multicenter study of IVC filters might help resolve some of the unanswered questions regarding filter efficacy and safety. ■

References

1. Mobin-Uddin K, Smith PE, Martinez LO, Lombardo CR, Jude JR. A vena caval filter for the prevention of pulmonary embolus. *Surg Forum* 1967; 18:209-211.
2. Mobin-Uddin K, Trinkle JK, Bryant LR. Present status of the inferior vena cava umbrella filter. *Surgery* 1971; 70:914-917.
3. McIntyre AB, McCreedy RA, Hyde GL, Mattingly W. A ten year follow-up study of the Mobin-Uddin filter for vena cava interruption. *Surg Gynecol Obstet* 1984; 158:513-516.
4. Greenfield LJ, McCurdy JR, Brown PP, Elkins RC. A new intracaval filter permitting continued flow and resolution of emboli. *Surgery* 1973; 73:599-606.
5. Greenfield LJ, Peyton R, Crute S, Barnes R. Greenfield vena caval filter experience: late results in 156 patients. *Arch Surg* 1981; 116: 1451-1456.
6. Greenfield LJ, Michna BA. Twelve year clinical experience with the Greenfield vena caval filter. *Surgery* 1988; 104:706-712.
7. Tadavarthy SM, Castaneda-Zuniga W, Salomonowitz E, et al. Kimray-Greenfield vena cava filter: percutaneous introduction. *Radiology* 1984; 151:525-526.
8. Rose BS, Simon DC, Hess ML, Van Aman ME. Percutaneous transfemoral placement of the Kimray-Greenfield vena cava filter. *Radiology* 1987; 165:373-376.
9. Denny DF, Dorfman GS, Cronan JJ, Greenwood LH, Morse SS, Yoselevitz M. Greenfield filter: percutaneous placement in 50 patients. *AJR* 1988; 150:427-429.
10. Pais SO, Tobin KD, Austin CB, Queral L. Percutaneous insertion of the Greenfield inferior vena cava filter: experience with 96 patients. *J Vasc Surg* 1988; 8:460-464.
11. Kantor A, Glanz S, Gordon DH, Sclafani SJ. Percutaneous insertion of the Kimray-Greenfield filter: incidence of femoral vein thrombosis. *AJR* 1987; 149:1065-1066.
12. Tobin KD, Pais SO, Austin CB. Femoral vein thrombosis following percutaneous placement of the Greenfield filter. *Invest Radiol* 1989; 24:442-445.
13. Dorfman GS. Percutaneous inferior vena caval filters. *Radiology* 1990; 174:987-992.
14. Grassi CJ. Inferior vena caval filters: analysis of five currently available devices. *AJR* 1991; 156:813-821.
15. Dorfman GS. Evaluating the roles and function of vena caval filters: will data be available before or after these devices are removed for the market? *Radiology* 1992; 185:15-17.
16. Roehm JOF, Johnsrude IS, Barth KH, Gianturco C. The bird's nest inferior vena cava filter: progress report. *Radiology* 1988; 168: 745-749.
17. Epstein DH, Darcy MD, Hunter DW, et al. Experience with the Amplatz retrievable vena cava filter. *Radiology* 1989; 172:105-110.
18. Simon M, Athanasoulis CA, Kim D, et al. Simon nitinol inferior vena cava filter: initial clinical experience. *Radiology* 1989; 172:99-103.
19. Ricco JB, Crochet D, Sebillotte P, et al. Percutaneous transvenous caval interruption with the LGM filter: early results of a multicenter trial. *Ann Vasc Surg* 1988; 3:242-247.
20. Greenfield LJ, Cho KJ, Pais O, Van Aman M. Preliminary clinical experience with the titanium Greenfield vena caval filter. *Arch Surg* 1989; 124:657-659.
21. Mansour M, Chang AE, Sindelar WF. Interruption of the inferior vena cava for the prevention of recurrent pulmonary embolism. *Am Surg* 1985; 51:375-380.
22. Spencer FC, Quattlebaum JK, Quattlebaum JK Jr, Sharp EH, Jude JR. Plication of the inferior vena cava for pulmonary embolism: a report of 20 cases. *Ann Surg* 1962; 155:827-837.
23. Miles RM, Richardson RR, Wayne L, Elsea PW, Stewart SB, Duncan D. Long term results with the serrated Teflon vena caval clip in the prevention of pulmonary embolism. *Ann Surg* 1969; 169:881-891.
24. Geisinger MA, Zelch MC, Risius B. Recurrent pulmonary emboli after Greenfield filter placement. *Radiology* 1987; 165:383-384.
25. Greenfield LJ, Cho KJ, Proctor M, et al. Results of a multicenter study of the modified hook-titanium Greenfield filter. *J Vasc Surg* 1991; 14:253-257.
26. Murphy TP, Dorfman GS, Yedlicka JW, et al. LGM vena cava filter: objective evaluation of early results. *JVIR* 1991; 2:107-115.
27. McCowan TC, Ferris EJ, Carver DK, Baker ML. Amplatz vena caval filters: clinical experience in 30 patients. *AJR* 1990; 155: 177-181.
28. Miller CL, Wechsler RJ. CT evaluation of Kimray-Greenfield filter complications. *AJR* 1986; 147:45-50.
29. McCowan TC, Ferris EJ, Carver DK. Inferior vena caval filter thrombi: evaluation with intravascular US. *Radiology* 1990; 177: 783-788.
30. Liu GC, Angtuaco TL, Ferris EJ, Shah HR, Reifsteck JE, Harshfield DL. Inferior vena caval filters: noninvasive evaluation. *Radiology* 1986; 160:521-524.
31. Millward SF, Marsh JJ, Peterson RA, et al. LGM (Vena Tech) vena cava filter: clinical experience in 64 patients. *JVIR* 1991; 2:429-433.

32. McCowan TC, Ferris EJ, Carver DK, Molpus WM. Complications of the nitinol vena caval filter. *JVIR* 1992; 3:401-408.
33. Carabasi RA, Moritz MJ, Jarrell BE. Complications encountered with the use of the Greenfield filter. *Am J Surg* 1987; 154:163-167.
34. Kupferschmid JP, Dickson CS, Townsend RN, Diamond DL. Small bowel obstruction from an extruded Greenfield filter strut: an unusual late complication. *J Vasc Surg* 1992; 16:113-115.
35. Greenfield LJ, Cho KJ, Pais SO, Van Aman M. Preliminary clinical experience with the titanium Greenfield filter. *Arch Surg* 1989; 124:657-659.
36. Teitelbaum GP, Jones DL, van Breda A, et al. Vena caval filter splaying: potential complication of use of the titanium Greenfield filter. *Radiology* 1989; 173:809-814.
37. McCowan TC, Ferris EJ, Reifsteck JE, Liu CC, Baker ML. Retrieval of dislodged bird's nest inferior vena caval filters. *J Intervent Radiol* 1988; 3:179-183.
38. Rogoff PA, Hilgenberg AD, Miller SL, Stepham SM. Cephalic migration of the Bird's Nest inferior vena caval filter: report of two cases. *Radiology* 1992; 184:819-823.
39. Messmer JM, Greenfield LJ. Greenfield filters: long-term radiographic follow-up study. *Radiology* 1985; 156:613-618.
40. Taheri SA, Kulaylat MN, Johnson E, Hoover E. A complication of the Greenfield filter: fracture and distal migration of two struts—a case report. *J Vasc Surg* 1992; 16:96-99.
41. Lang W, Schweiger H, Fietkau R, Hofmann-Preiss K. Spontaneous disruption of two Greenfield vena caval filters. *Radiology* 1990; 174:445-446.
42. Awh MH, Taylor FC, Lu CT. Spontaneous fracture of a Vena-Tech inferior vena caval filter. *AJR* 1991; 157:177-178.
43. Mewissen MW, Erickson SJ, Foley WD, et al. Thrombosis at venous insertion sites after inferior vena caval filter placement. *Radiology* 1989; 173:155-157.
44. Dorfman GS, Cronan JJ, Paolella LP, et al. Iatrogenic changes at the venotomy site after percutaneous placement of the Greenfield filter. *Radiology* 1989; 173:159-162.
45. Hicks ME, Middleton WD, Picus D, Darcy MD, Kleinhoffer MA. Prevalence of local venous thrombosis after transfemoral placement of a Bird's Nest vena caval filter. *JVIR* 1990; 1:63-68.
46. Molgaard CP, Yucel EK, Geller SC, Knox TA, Waltman AC. Access-site thrombosis after placement of inferior vena cava filters with 12-14-F delivery sheaths. *Radiology* 1992; 185:257-261.
47. Vesely T, Darcy M, Picus D, Hicks M. Technical problems associated with placement of the Bird's Nest inferior vena cava filter. *AJR* 1992; 158:875-880.
48. Kastan DJ, Forcler NJ, Kahn ML, Simon nitinol vena cava filter: preliminary observations and suggested procedural modifications. *JVIR* 1991; 2:123-124.
49. Reed RA, Teitelbaum GP, Taylor FC, et al. Incomplete opening of LGM (Vena Tech) filters inserted via the transjugular approach. *JVIR* 1991; 2:441-445.
50. Millward SF, Marsh JJ, Peterson RA, et al. LGM (Vena Tech) vena cava filter: clinical experience in 64 patients. *JVIR* 1991; 2:429-433.

Domir
BernVei
of a

Efficiency
Tech-LGM
patients p
a 2-6-year
tients wer
(91.3%) scl
tions were
tients died
thromboei
embolism
viving pat
tions (18.4%
(18.4%), an
Filter pate
trasonogra
phlebocav
ing results
Meier 2
after 2
years, and
Tech-LGM
lated to rel
migration
trophic dis
during the
lated to the
nous thron
relation to
The filter v
pulmonary
onstrating
deleterious
obstruction
up.

Index terms:
Venae cavae, :
982.1267 • Ve
982.721

Radiology 195

¹ From the I
Hemodynami
nec-CHR Nan
ceived Ser
Novemb
1993; acce
quests to D.P.
© RSNA, 199